

Notice of Allowability

Application No.

10/815,747

Applicant(s)

TERRY ET AL.

Examiner

Art Unit

Gailene R. Gabel

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to application submitted on 4/2/04 and interview summary on 10/12/06.
2. ☒ The allowed claim(s) is/are 1-19, respectively.
3. ☒ The drawings filed on 02 April 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 4/2/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 10/12/06
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Gabel
10/12/06

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this examiner's amendment was given in a telephone interview with Dana Tangren on October 12, 2006.

3. The application has been amended as follows:

In the first sentence of the specification at page 1, line 1, after "continuation of", "co-pending" has been deleted. Further after "filed on January 8, 1999,", --now US Patent Number 6,790,652-- has been inserted.

In line 2 of the preamble of claim 2, after "layer", --comprising-- has been inserted.

- Further in line 2 of the preamble after, "physiologically viable cells," "wherein the cells" has been deleted, and --that-- has been inserted therefor.

- Further in lines 3-5 the preamble, "wherein the porous membrane is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side," has been deleted.

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- Further in line 5 of the preamble, --the method-- has been inserted before the transition language, "comprising:".

In claim 2, line 6 step a), "(a)" has been deleted and --(b)--has been inserted therefor.

In claim 2, line 6, step a) has been inserted as follows:

-- (a) growing the cells on the porous membrane which is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side;--.

In claim 2, step b), "(b)" has been deleted and --(c)-- has been inserted therefor.

- Further in *amended* step (c) after "in close apposition with the detector layer", --having a liquid layer overlain thereto" has been inserted--.

Accordingly, claim 2 reads as follows:

2. A method for simultaneously exposing an array of test compounds to a detector layer comprising of physiologically viable cells that are grown on a porous membrane, the method comprising:

(a) growing the cells on the porous membrane which is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side;

(b) providing an array of test compounds, wherein the test compounds are disposed on a support;

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(c) bringing the array of test compounds in close apposition with the detector layer having a liquid layer overlain thereto so that the porous membrane is in contact with the array of test compounds thereby allowing diffusion of the test compounds through the porous membrane to the detector layer of physiologically viable cells.

In claim 4, after "according to any", --one-- has been inserted.

In claim 5, after "according to any", --one-- has been inserted.

In claim 6, after "according to any", --one-- has been inserted.

In claim 7, after "according to any", --one-- has been inserted.

In claim 8, after "according to any", --one-- has been inserted.

In line 2 of the preamble of claim 10, after "detector layer", --comprising-- has been inserted.

- Further in line 2 of the preamble after, "physiologically viable cells," ",wherein the cells" has been deleted, and --that-- has been inserted therefor.

- Further in line 3 of the preamble after, "are grown on" ",the" has been deleted, and --a-- has been inserted therefor.

- Further in lines 3-5 the preamble, "wherein the porous membrane is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side," has been deleted.

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- Further in line 5 of the preamble, --the method-- has been inserted before the transition language, "comprising:".

In claim 10, line 6 step a), "(a)" has been deleted and --(b)--has been inserted therefor.

In claim 10, line 6, step a) has been inserted as follows:

-- (a) growing the cells on the porous membrane which is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side;--.

In claim 10, *amended* step b) after "providing an array of test compounds", -- wherein the test compounds are disposed on a support-- has been inserted.

In claim 10, step b), "(b)" has been deleted and --(c)-- has been inserted therefor.

- Further in *amended* step (c) after "in close apposition with the detector layer", -- having a liquid layer overlain thereto" has been inserted--.

In claim 10, step c), "(c)" has been deleted and --(d)-- has been inserted therefor.

Accordingly, claim 10 reads as follows:

10. A method for screening test compounds for bioactivity by simultaneously exposing an array of test compounds to a detector layer comprising of physiologically viable cells that are grown on a porous membrane, the method comprising:

- (a) growing the cells on the porous membrane which is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side;**
- (b) providing an array of test compounds, wherein the test compounds are disposed on a support;**
- (c) bringing the array of test compounds in close apposition with the detector layer having a liquid layer overlain thereto so that the porous membrane is in contact with the array of test compounds thereby allowing diffusion of the test compounds through the porous membrane to the detector layer of physiologically viable cells.**
- (d) detecting a response of the detector layer to the test compound.**

In claim 11, after "according to any", --one-- has been inserted.

In claim 12, after "according to any", --one-- has been inserted.

In claim 13, after "according to any", --one-- has been inserted.

In claim 15, after "according to any", --one-- has been inserted.

In claim 16, after "according to any", --one-- has been inserted. Further in claim

16, line 2 after "viable cells are", --further-- has been inserted.

In claim 17, after "according to any", --one-- has been inserted.

In claim 18, after "according to any", --one-- has been inserted.

In claim 19, after "according to any", --one-- has been inserted.

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4. The following is an examiner's statement of reasons for allowance:

A) The prior art of record does not teach or fairly suggest exposing an array of test compounds disposed on a porous membrane, to a monolayer of physiologically viable cells supported by substrate, wherein the porous membrane is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side, so that upon close apposition of the array of test compounds disposed on the porous membrane with the monolayer of cells overlain with a liquid layer, the test compounds are caused to be allowed to diffuse through the pores of the porous membrane to the detector layer of cells.

B) The prior art of record does not teach or fairly suggest exposing an array of test compounds disposed on a support to a monolayer of physiologically viable cells that are grown on a porous membrane which is constructed of a non-absorbent material with pores of regular and defined diameter which traverse the membrane directly from the upper to the lower side, so that upon close apposition of the array of test compounds disposed on the support with the monolayer of cells on the porous membrane and overlain with a liquid layer, the test compounds are caused to be allowed to diffuse through the pores of the porous membrane into the detector layer of cells.

C) The closest prior art are Beutel et al. (US Patent 5,976,813) and Chelsky et al. (US 5,856,083).

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Beutel et al. disclose continuous format high throughput screening (CF-HTS) of test compounds generated by combinatorial chemistry using a porous membrane (matrix) to allow an array of test compounds to be simultaneously exposed to a detector layer comprising physiologically viable cells (cell matrix) for detection of cellular response to the test compounds. However, the porous matrix of Beutel et al., is formed of absorbent material having no defined diameter or porosity, and functions by random multidirectional and lateral diffusion of compounds through the absorbent porous matrix.

Chelsky et al. disclose a porous colloidal matrix through which test compounds can be diffused for exposure to a cell layer in a lawn assay method. The porous colloidal matrix taught by Chelsky, however, is formed of absorbent material having no defined diameter or porosity, and functions by random multidirectional and lateral diffusion of compounds through the absorbent porous matrix.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, Thursday from 7:30 AM to 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
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October 12, 2006